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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,915	PELLICO, MICHAEL A.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Informalities

In claim 16, the phrase "in the absence of", while not indefinite *per se*, is in poor grammatical form. The examiner recommends amending the claim to recite a "tooth bleaching gel comprising carbamide peroxide and aqueous hydrogen peroxide, wherein said composition does not contain a radiant energy or heat energy activator substance."

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The percentage values recited by instant claims 13-15 are unclear because they do not include the basis for their measurement, e.g. by weight, volume, mole, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite where the method of measurement is not also specified).

2) Claims 13-15 contain the following trademark/trade names: "Klucel GF" or "Klucel GFF"; "CAB-O-SIL EH-5"; and "Polawax NF". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular

material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe various claimed additives and, accordingly, the identification/description is indefinite.

3) Note also that the duplicate recitation of a major and minor recitation of the same component, i.e., the recitation of propylene glycol USP twice in claim 13, and glycerin USP twice in claims 14 and 15, while not indefinite *per se,* is in poor form. No logical reason exists for using this duplicate format; it would be far clearer to simply recite the component once. As an example, rather than reciting 33.000 percent and 8.900 percent propylene glycol USP in claim 13, it makes far more sense to simply recite their total, i.e. to recite propylene glycol USP once in an amount of 41.900 percent.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Chadwick et al (USP 6,555,020).

Claim 1 of the prior art recites an aqueous dental bleaching gel comprising "at least one bleaching agent selected from the group consisting of hydrogen peroxide and compounds that release hydrogen peroxide". The specification discloses only one example of compounds that release hydrogen peroxide, namely carbamide peroxide (col. 4, lines 39-46); that species is specifically recited in claim 2 of

the patent as well. This effectively means that claim 1 encompasses only three possible bleaching agents: 1) hydrogen peroxide 2) carbamide peroxide and 3) a mixture of hydrogen peroxide and carbamide peroxide. Since a selection need only be made from a very limited group, since the phrase "at least one" is tantamount to a discrete disclosure of a mixture, and since the only choice for the additional agent in the mixture is carbamide peroxide, the prior art appears to be sufficiently specific to be anticipatory of instant claim 16. (Insofar as the examiner can determine, the prior art does not disclose incorporating a radiant energy of heat energy activator substance).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-10 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332).

The primary reference discloses a two-chambered syringe for tooth whitening, where the first chamber contains peroxide, and the second contains a basic element (col. 3, lines 47-53). The basic element contains a basic compound such as sodium hydroxide to increase its pH (col. 5, lines 19-27).

The peroxide and basic element are admixed prior to application (col. 3, lines 54-57), and thus are "adapted to be admixed and applied to the teeth from a dental tray for sustained contact" as required by the instant preamble. The compositions of the primary reference are preferably provided in gel form: see col. 5, lines 55-60. When used by the patient, the components of the first and second chambers are dispensed from the syringe into a bleaching tray while mixing the components together to form an active bleaching gel, just as is done in instant claims 25-32. See col. 8, lines 36-49.

The primary reference differs from the instant claims insofar as it does not specifically disclose a mixture of hydrogen peroxide and carbamide peroxide, instead teaching the use of each singly, with hydrogen peroxide being preferred. (Col. 5, lines 50-54).

The secondary reference teaches that where it is known to use carbamide peroxide and hydrogen peroxide individually as active agents in a particular bleaching gel, it is further known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations" (col. 5, lines 59-63), i.e., a varied spectrum of bleaching activity (with carbamide peroxide acting more slowly than hydrogen peroxide). The secondary reference differs from the instant claims insofar as it is limited to one-component systems, rather than two-component systems as required instantly.

It would have been obvious to have combined the individually disclosed hydrogen and carbamide peroxides of the primary reference bleaching gels in varying concentrations, motivated by the desire to provide bleaching compositions having a wide spectrum of bleaching activities, as taught by the secondary reference.

Regarding dependent claims 3-10, it is well-settled that, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not kind; experimentation to find *workable* conditions generally involves the application of no more than routine skill. See In re Aller 105 USPQ 233, 235 (CCPA 1955). Similarly, the determination of optimal values is generally considered obvious. In re Boesch, 205 USPQ 215 (CCPA 1980). See also In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). (That court reaffirming the previous Aller and Boesch decisions, stating at page 1330 that: "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the

motivation to determine where in a set of disclosed percentage ranges is the optimum combination of percentages.") Accordingly, it would have been obvious to one skilled in the art, having arrived at the subject matter of instant claim 1, to have routinely tested various relative concentrations of carbamide and hydrogen peroxide to determine workable/optimal values, consonant with the reasoning of the above-cited precedent.

Regarding dependent claim 2, the primary reference teaches the use of the gelling agent hydroxyethylcellulose (col. 5, line 57), rather than hydroxpypropylcellulose. It is well-settled, however, that a prima facie case of obviousness may be based upon structural similarity, i.e., an established structural relationship between a prior art compound and a claimed compound, such as homology or position isomerization. See In re Deuel, 51 F.3d 1532, 1559 (Fed. Cir. 1995); the necessary motivation to make the claimed compound, and thus the prima facie case of obviousness, arises from the reasonable expectation that compounds similar in structure will have similar properties. See In re Grabiak 769 F.2d 729, 733 (1985); see also In re Gyurik, 596 F.2d 1012 (CCPA 1979). Accordingly, it would have been obvious to have used hydroxypropylcellulose in place of hydroxyethylcellulose as the gelling agent of the primary reference compositions, motivated by the reasonable expectation that two compounds, which are similar in structure (related essentially as homologues), would have correspondingly similar gelling properties, consonant with the reasoning of the cited precedent.

2) Claims 11, 12, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332), the combination being taken further in view of Norfleet (USP 5,486,350).

The primary and secondary references, and the rationale for combining their teachings, are discussed in detail in subsection "1)" supra. The subject matter fairly suggested by their combined teachings differs from the instant claims insofar as the incorporation of sodium fluoride and potassium nitrate (claims 11 and 33), or potassium nitrate and tetrapotassium pyrophosphate (claims 12 and 34) is not specified.

The tertiary reference teaches that it is well-known to incorporate these additional ingredients into dentrifices. Specifically, mixtures of potassium nitrate and tetrapotassium pyrophosphate are used to reduce tooth sensitivity (col. 1, lines 9-18, for example), with sodium fluoride being used to stabilize the pyrophosphate (col. 4, lines 37-49). The tertiary reference differs from the instant claims insofar as it does not specifically disclose bleaching gels (a type of dentrifice).

It would have been obvious to have added sodium fluoride, potassium nitrate and tetrapotassium pyrophosphate to the bleaching gels suggested by the combined teachings of the primary and secondary references, motivated by the desire to increase the comfort of patients having sensitive teeth while undergoing the bleaching procedure, since those compounds are known sensitivity reducers as taught by the tertiary reference.

3) Claims 17-24 are rejected under 35 USC 103(a) as being unpatentable over Chadwick et al (USP 6,555,020) in view of Jensen et al (USP 5,858,332).

The primary reference discloses aqueous dental gels comprising hydrogen peroxide or carbamide peroxide, the total amount of bleaching agent ranging from 3 to 50 percent by weight of the gel (col. 4, lines 33-46). Claim 1 recites the use of "at least one" bleaching agent, thus teaching the use of mixtures. Specific combinations, i.e. exemplified combinations with specified percentages of each agent, are not specified, however, as required by the instant claims.

The secondary reference teaches that where it is known to use carbamide peroxide and hydrogen peroxide individually as active agents in a particular bleaching gel, it is further known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations" (col. 5, lines 59-63), i.e., a varied spectrum of bleaching activity (with carbamide peroxide acting more slowly than hydrogen peroxide). The secondary reference differs from the instant claims insofar as it is limited to one-component systems, rather than two-component systems as required instantly.

It would have been obvious to have combined the individually disclosed hydrogen and carbamide peroxides of the primary reference bleaching gels in varying concentrations, motivated by the desire to

provide bleaching compositions having a wide spectrum of bleaching activities, as taught by the secondary reference.

4) Claims 16-24 are rejected under 35 USC 103(a) as being unpatentable over Fischer (USP 5,725,843) in view of Jensen et al (USP 5,858,332).

The primary reference discloses aqueous dental bleaching gels comprising a bleaching agent. The reference clearly teaches that the "concentration of dental bleaching agent may vary depending on its reactivity", with either 3 to 20 percent by weight carbamide peroxide, or 2 to 10 percent by weight hydrogen peroxide being preferred. See col. 4, lines 54-63. The primary reference differs from the instant claims, however, insofar as it silent regarding mixtures of bleaching agents.

The secondary reference teaches that where it is known to use carbamide peroxide and hydrogen peroxide individually as active agents in a particular bleaching gel, it is further known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations" (col. 5, lines 59-63), i.e., a varied spectrum of bleaching activity (with carbamide peroxide acting more slowly than hydrogen peroxide). The secondary reference differs from the instant claims insofar as it is limited to one-component systems, rather than two-component systems as required instantly.

It would have been obvious to have combined the individually disclosed hydrogen and carbamide peroxides of the primary reference bleaching gels in varying concentrations, motivated by the desire to provide bleaching compositions having a wide spectrum of bleaching activities, as taught by the secondary reference.

Allowable Subject Matter

Claims 13-15 would be allowable if rewritten to include the limitations of all intervening claims, and to overcome the outstanding rejections under 35 U.S.C. 112, second paragraph.

The prior art of record does not fairly suggest, teach or disclose the particular two component systems of the instant claims. The closest prior art, Ostler (USP 6,116,900), provides no direction for selecting the particular combinations of specific ingredients recited therein, let alone in the specific percentages set forth therein. (Indeed, it is completely silent regarding the use of polyol diluents generally, let alone the specific diluents propylene glycol and glycerine). Moreover, while some variation in the composition of tooth bleaching gels for the purposes of optimization might be generally obvious, it is well-known in the art that substantial changes can have unpredictable effects, and this unpredictability would only be compounded where the bleaching gel was divided into different functional components. See for example USP 5,858,332 at col. 6, lines 30-33. To arrive at the complex mixtures recited in claims 13-15 would require far more than routine experimentation/optimization, the effects of which could not be reasonably predicted from the facts of record.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614